

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BRISTOL MYERS SQUIBB :
COMPANY, :
 : Civil Action No. 23-3335(ZNQ)(JBD)
 :
Plaintiff, :
 :
v. : Hon. Zahid N. Quraishi
 : Hon. J. Brendan Day
XAVIER BECERRA, U.S. Secretary of :
Health & Human Services; *et al.*, :
 :
Defendants. :
 :

**PLAINTIFF'S COMBINED OPPOSITION TO DEFENDANTS' MOTION
FOR SUMMARY JUDGMENT AND REPLY IN SUPPORT OF
PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT**

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PRELIMINARY STATEMENT

The so-called “Drug Price Negotiation Program” (the Program) of the Inflation Reduction Act (IRA) seeks to require Bristol Myers Squibb (BMS) to transfer one of its most valuable products, Eliquis, to Medicare beneficiaries at a steep discount, pay huge financial penalties, or forfeit access to half the nation’s prescription drug market. To disguise the unprecedented and coercive nature of this regime, Congress also requires BMS to “agree” that this discounted price is the “maximum fair” price for its medicine, reached through what the Government calls voluntary “negotiations.”

As BMS explained, the Program violates the Fifth and First Amendments on its face. The Takings Clause prohibits the Government from taking BMS’s property for public use without paying fair market value. And the First Amendment prohibits the Government from compelling BMS to feign “agreement” with this scheme.

In response, the Government tries to paper over these constitutional violations by characterizing the Program as “voluntary.” But the Program forces an unconstitutional choice—either surrender medicines while echoing the Government’s message, or pay ruinous penalties. The notion that BMS can avoid the Program’s mandates by divesting Eliquis is as absurd as it sounds; jettisoning property to avoid its appropriation hardly solves the problem. Nor can the Government shield the Program from scrutiny by claiming that BMS can withdraw *all* its products from Medicare and Medicaid—leaving millions of patients without life-saving medicines and forfeiting access to nearly half of the U.S. prescription drug market. The unconstitutional

conditions doctrine prevents the Government from using its market power to coerce BMS to abandon constitutional rights. Yet that is exactly how the Program operates—it leverages a massive, pre-existing funding stream for *other* products, a source of revenue critical to any pharmaceutical company’s viability, to coerce BMS to surrender its property and to pretend it did so voluntarily. This is a Hobson’s choice—a coercive, disproportionate threat that compels BMS to submit to the Program’s mandates.

Congress could have simply imposed “limits on how much federal agencies pay for prescription drugs.” Govt. Br. 1. Or it could have directed agencies to genuinely “negotiate prices”—giving BMS a real choice whether to sell. *Id.* But the Constitution prohibits the Government from using draconian penalties and exclusion from federal benefits to punish manufacturers who refuse to “agree” to sell their medicines at fire-sale prices. That is a textbook abuse of the Spending Clause to evade the Bill of Rights.

ARGUMENT

I. THE PROGRAM VIOLATES THE FIFTH AMENDMENT BY TAKING BMS’S PRIVATE PROPERTY WITHOUT JUST COMPENSATION.

As BMS explained, Eliquis is private property. The Program effects a taking of Eliquis by threatening to penalize BMS, either through a financial penalty or exclusion from other government benefits, unless BMS provides Medicare beneficiaries with “access” to the medicine at a discounted price. And that price cannot provide “just compensation” because it is capped at a *fraction* of Eliquis’s market price. This scheme, on its face, violates the Fifth Amendment’s Takings Clause.

The Government claims there is no taking because BMS supposedly has several “options” to avoid the Program’s mandates. Govt. Br. 6, 17. It starts by claiming that those “options” make the Program “voluntary.” Govt. Br. 13–19. And it ends, similarly, by asserting that the Program operates as a “condition on federal funds.” Govt. Br. 36–38. But a methodical review exposes the Government’s shell game. In theory, BMS has four options: (i) submit to forced below-market sales of Eliquis, *infra* Part I.A; (ii) pay draconian fines for refusing to surrender its property, *infra* Part I.B; (iii) abandon its property interest in Eliquis altogether in order to avoid the taking, *infra* Part I.C; or (iv) forfeit nearly half the U.S. prescription drug market by unilaterally withdrawing all of its life-saving medicines from Medicare and Medicaid, *infra* Part I.D. In truth, BMS has no *real* “choice” here. Its “options” are just one unconstitutional imposition after another.

A. The Program’s Compelled Sales of Eliquis Take BMS’s Property.

To start, BMS’s most obvious option—the one the Program actually *commands* it to take—is to provide Medicare beneficiaries with “access” to Eliquis at whatever price the Government dictates. *See* 42 U.S.C. § 1320f–3(a) (directing that manufacturer “*shall* ... negotiate a maximum fair price”); *id.* § 1320f–2(a)(3) (ordering that “access to the maximum fair price ... *shall* be provided” by manufacturer) (emphases added). As the Government recognizes, that is where the constitutional analysis must begin—because the threshold inquiry is whether the “funding condition ... could be constitutionally imposed directly.” Govt. Br. 36 (quoting *Rumsfeld v. FAIR*, 547 U.S. 47, 59 (2006)).

A flat directive to provide “access” to Eliquis would undoubtedly be a physical taking. Eliquis is property under the Fifth Amendment. *See Horne v. Dep’t of Agric.*, 576 U.S. 351, 358 (2015). A government order to provide property (Eliquis) to third parties (Medicare beneficiaries) takes that property. *See Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063, 2072 (2021). And promising to pay a price below “market value” bears only on the *amount* of compensation owed; it does not change that a taking has occurred. *Horne*, 576 U.S. at 368–69; *see also id.* at 363–64 (holding that partial recoupment of proceeds from appropriated property goes only to quantum of damages). Although the Government will not send “trucks” to BMS’s warehouse to “haul away” Eliquis, Govt. Br. 28, the Constitution does not care how an appropriation “comes garbed,” *Cedar Point*, 141 S. Ct. at 2072. The Program’s forced sales are functionally equivalent to physically seizing the medicine from the warehouse—the Program takes Eliquis from BMS and gives it to third parties without paying its market price.

Focusing for now on BMS’s “option” of submitting to these forced sales, the Government’s few counterarguments lack merit. *See* Govt. Br. 25–28.

The Government first argues that manufacturers have no “property interest in Medicare sales” (Govt. Br. 26), but that is a misdirection. The Program effects takings by *compelling* sales of Eliquis to Medicare, not *depriving* BMS of those sales. In other words, BMS’s property interest is in Eliquis itself, not Medicare revenue. BMS is not trying to “*force* [its] drugs onto the government at rates the government is unwilling to pay” (Govt. Br. 27); it is resisting the Program’s obligation to *transfer* Eliquis to Medicare

at rates the Government dictates and to which BMS would never ordinarily agree. To use the Government’s hypothetical, a defense contractor cannot force the Pentagon to buy its aircraft carrier (*id.*), but mandating the contractor to provide the Navy with “access” to the vessel would just as obviously be a classic, physical, *per se* taking.

Next, the Government claims that the Program does not “take” drugs because the Program does not obligate BMS to provide “access” to *Eliquis*, only “access” to a *discounted price* for Eliquis. Govt. Br. 28–29. But that is just wordplay—access to a *price* necessarily means access to the *product*. If, after signing the agreement with CMS, BMS were to refuse to transfer Eliquis to Medicare at the “maximum fair price,” BMS would plainly be violating the Program’s “access” mandate. It would be like a car dealer entering a contract to sell one of its vehicles to a customer at 60% off, but then refusing to let the customer onto the lot to pick up the car.

Indeed, the Government eventually concedes that BMS and other manufacturers have an “obligation” under the Program “to ultimately *provide their drugs* at the negotiated prices.” Govt. Br. 38 (emphasis added). Likewise, it admits that (unless a manufacturer opts out of Medicare and Medicaid entirely) the Program requires them to “make their drugs available” at the dictated prices. Govt. Br. 2; *see also* IRS, Notice 2023-52, at 2 (Aug. 4, 2023) (manufacturers must “provide *access to selected drugs*” (emphasis added)). Moreover, the IRA further requires that selected drugs “shall” be included in *every* Medicare Part D drug formulary, thereby plainly stripping BMS of the right to withhold Eliquis from coverage. 42 U.S.C. § 1395w–104(b)(3)(I)(i).

The Government’s insinuation that BMS could comply with the Program by refusing to sell Eliquis to Medicare (while its other medicines continue to be covered) is thus plainly wrong. To be sure, BMS has the “option” to suspend the IRA’s penalties by withdrawing *all* its products from Medicare and Medicaid; the constitutional inadequacy of that course is discussed below. *See infra* Part I.D. But again, that requires the manufacturer to “withdraw[] *all of its drugs* from federal healthcare programs.” *Dayton Area Chamber of Com. v. Becerra*, No. 3:23-cv-156, 2023 WL 6378423, at *2 (S.D. Ohio Sept. 29, 2023) (emphasis added). Absent that, BMS must provide Medicare beneficiaries with “access” to Eliquis, not withhold it. Indeed, it would make no sense for the IRA to suspend its tax only if a manufacturer withdraws *all* products from Medicare and Medicaid, yet permit manufacturers to circumvent that all-or-nothing choice by declining to sell *only* the selected medicine to Medicare, as the Government hints. Govt. Br. 14, 29. Transfer of Eliquis to Medicare beneficiaries is thus *legally compelled* by the Program’s “access” requirement.¹

¹ At points, the Government tries to get to the same place through a back door: suggesting BMS would face *no penalty* for refusing to sell Eliquis to Medicare, since the IRA’s tax penalty applies only to sales *to Medicare*. Govt. Br. 8, 17. That too is wrong. The statute is clear: the tax applies to “the sale ... of any designated drug,” 26 U.S.C. § 5000D(a)—with no limitation based on who the *buyer* is. The Government’s contrary view would upend the scheme by letting manufacturers avoid the IRA’s penalties by withdrawing only the selected medicine from Medicare, even though Congress provided for suspension of the penalty only if the manufacturer withdraws *all* of its products. Again, Congress did not put manufacturers to a painful all-or-nothing choice, only to construct a halfway house through a tax loophole. The IRS’s vague notice announcing an intent to promulgate regulations in the future changes none of that.

In short, to comply with the mandate to provide “access” to the “maximum fair price” for Eliquis, BMS must physically provide *Eliquis* at that price. That forced transfer is a taking. *See Cedar Point*, 141 S. Ct. at 2072 (requiring “access” to property was *per se* taking). And it distinguishes this novel Program from mere price regulation. Unlike with the latter, BMS is “‘legally compelled to engage in price-regulated activity,’” which even the Government concedes triggers the Takings Clause. Govt. Br. 12.

Finally, the Government never disputes that the Program’s ceiling price for Eliquis falls below the “market value” of the medicine. *Horne*, 576 U.S. at 368–69. BMS’s challenge to the Program is therefore appropriately facial, because the Program fails to provide just compensation for the property it takes in *all* applications. And because BMS seeks only declaratory relief on this claim, there is no need for the Court to determine the actual market value of Eliquis. *See* BMS MSJ Br. 19–22.

Nevertheless, the Government suggests that BMS’s takings claim must be directed toward the ultimate “rates, not methods,” by analogizing to public utilities. Govt. Br. 30 (quoting *Verizon Commc’ns Inc. v. FCC*, 535 U.S. 467, 525 (2002)). But BMS is not challenging the Program’s price-setting “method” in the abstract, so *Verizon* is inapposite. The point here is that the “rates” capped by the Program are pegged to a *fraction* of the market price for Eliquis and so *necessarily* do not provide market value. *See United States v. Gen. Motors*, 323 U.S. 373, 385 (1945) (Douglas, J., concurring in part) (finding it “difficult to see” how “allow[ing] the Government to ... pay only a part of the rent” for leasehold would provide just compensation). Here, unlike in *Verizon*, the

face of the statute makes clear that the Program’s prices will fall below just compensation. There is no need to wait for CMS to choose a “particular” rate for Eliquis when the rate will necessarily be below the market price. Govt. Br. 30.²

The Government’s arguments ultimately fail to obscure reality: The Program’s forced sales of Eliquis are takings, and it is undisputed that the Program fails to provide market-rate compensation. This “option” thus plainly violates the Fifth Amendment.

B. The Government Cannot Circumvent the Takings Clause by Penalizing BMS’s Refusal To Surrender Eliquis.

The Government claims the Program is voluntary because a “manufacturer that does not wish to sign ... an agreement” can just “pay an excise tax.” Govt. Br. 6; *see* 26 U.S.C. § 5000D. But the penalty does not *remedy* the taking—it *enforces* it. The penalty is the mechanism to effectuate the taking. *See Horne*, 576 U.S. at 356 (demand for raisins imposed through penalty was a taking); BMS MSJ Br. 16-17 (citing other cases).

² While the Government does not dispute that the Program’s ceiling prices fail to provide just compensation, a set of *amici* argue that the market prices of prescription medicines are not “fair” because manufacturers enjoy a period of exclusivity under patent and FDA law. *See* Public Citizen Br. 9–15. As an initial matter, *amici* cannot raise issues the parties forfeited. *See In re Lan Assocs. XI, L.P.*, 192 F.3d 109, 115 n.5 (3d Cir. 1991). Regardless, the Supreme Court has long endorsed “market price” as the measure of just compensation for property bought and sold in an established market, *Kimball Laundry Co. v. United States*, 338 U.S. 1, 6 (1949), and there is no question that a market exists for patented, prescription medicines. *Amici* cite no authority suggesting any different standard. Nor should there be one: The exclusivity to which they object is an intentional innovation-inducing *feature* of this market—not a *bug*. *See, e.g., United States v. Gen. Electric*, 272 U.S. 476, 489 (1926) (patent law protects “the reward which the patentee by the grant of the patent is entitled to secure”); *King Instruments Corp. v. Perego*, 65 F.3d 941, 950 (Fed. Cir. 1995) (patent law “creates an incentive for innovation” by ensuring “economic rewards during the period of exclusivity”).

A recent decision sustaining a Takings Clause challenge to another federal statute that requisitions property using the threat of fines proves the point. *Valancourt Books, LLC v. Garland*, 82 F.4th 1222 (D.C. Cir. 2023). As discussed further below, *Valancourt* involved a challenge to a provision of the Copyright Act that orders the owner of a copyright in a work to “deposit two copies of the work with the Library of Congress.” *Id.* at 1226. If the owner fails to do so, it must “pay a fine.” *Id.* The D.C. Circuit made clear that the choice of paying the fine did not eliminate the taking. The owners could “pay[] a fine instead of forfeiting their property,” the court noted. *Id.* at 1234. But that did not “affect[] the analysis,” as a fine equally “burdens” property rights. *Id.* Any other rule would let the Government “avoid” the Takings Clause “by purporting to ‘simply give the owner a choice of either surrendering property or making a payment equal to the property’s value.’” *Id.* at 1235.

In short, the Program directs BMS either to provide “access” to Eliquis at a discount or pay monetary penalties. That “choice” itself violates the Constitution.³

³ The Government claims that BMS misunderstands the *amount* of the tax for refusing to make the forced sales. Govt. Br. 17. The amount of the tax makes no constitutional difference; penalizing the refusal to abandon property rights violates the Fifth Amendment in any case. Indeed, the fine in *Valancourt* was just \$250, and that sufficed to make the scheme unconstitutional. *See* 82 F.4th at 1232, 1234-35. Regardless, BMS’s understanding accords with the Congressional Research Service. *See* Cong. Rsch. Serv., R47202, *Tax Provisions in the Inflation Reduction Act of 2022*, tbl. 2 (2022) (explaining that tax would reach “1,900% of the selected drug’s price”). The Government cites an IRS notice that tries to rewrite the statute amidst litigation to make it appear less draconian; such efforts are not only irrelevant but also futile, given that an “agency may not rewrite clear statutory terms.” *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 328 (2014).

C. BMS’s Ability To Divest Its Interest in Eliquis Before the Taking Does Not Cure the Constitutional Problem.

Next, the Government offers that BMS could avoid the Program’s mandates if it “divest[s] [its] interest” in Eliquis. Govt. Br. 8; *see also* Govt. Br. 2, 14, 17, 23, 24. To be clear, however, BMS could not simply spin off Eliquis to a subsidiary or affiliate—CMS guidance clarifies that the divestment must involve an *unrelated* party. ECF 36-2 at 135–36. The Government’s argument, then, is that BMS can escape the taking of Eliquis by selling off its property rights before Medicare takes them from it—thereby instead saddling *the buyer* with the appropriation and a corresponding takings claim.

This “option” solves the taking no better than paying a fine. Transferring BMS’s property “burdens ownership of property.” *Valancourt*, 82 F.4th at 1234-35. Indeed, divesting Eliquis strips BMS of all of the same property rights as the taking itself—BMS would transfer “title” and “lose any right to control” Eliquis. *Horne*, 576 U.S. at 364. By way of analogy, if the Government announced an intent to seize your house in 30 days, your ability to quickly sell the house instead obviously would not erase the violation of the Fifth Amendment.

Indeed, the Court rejected a similar argument in *Horne*: that the Government had not taken the raisin crop because the growers could just “plant different crops” or “sell their raisin-variety grapes as table grapes or for use in juice or wine.” 576 U.S. at 365. That theory is wrong “as a matter of law,” the Court explained, because “basic and familiar uses of property” cannot be recharacterized as “special governmental benefit[s]

that the Government may hold hostage, to be ransomed by the waiver of constitutional protection.” *Id.* at 365–66. Likewise, in *Loretto v. Teleprompter Manhattan CATV Corp.*, the Court rejected an argument that no taking occurred because the “landlord could avoid the requirements of [the statute] by ceasing to rent the building to tenants.” 458 U.S. 419, 439 n.17 (1982). Property rights “cannot so easily be manipulated.” *Id.*

These cases foreclose the Government’s “divest” theory. BMS can surrender “access” to Eliquis, pay a penalty, or abandon its property before the Government appropriates it. As in *Horne* and *Loretto*, that false choice violates the Takings Clause.

D. Terminating Medicare and Medicaid Coverage for All of BMS’s Products Is a Coercive, Disproportionate, Unlawful Penalty.

Finally, the principal “option” the Government floats to avoid the Program’s mandates is that BMS can suspend the IRA’s tax penalty by withdrawing all of its products from Medicare and Medicaid. According to the Government, this “choice” renders the Program entirely “voluntary” just like any other ordinary condition on a government benefit. *See* Govt. Br. 12–15. But that argument fails on multiple levels. The “option” to withdraw from Medicare and Medicaid is not a genuine offer tied to the Program’s scope or objectives; rather, it is a cudgel to coerce BMS’s compliance by threatening exclusion from distinct, pre-existing funding streams that are critical to manufacturers’ viability. In this context, holding hostage all Medicare and Medicaid coverage to coerce a separate transfer of property is not a constitutionally permissible option under the Supreme Court’s unconstitutional conditions doctrine.

1. The IRA does not treat Medicare and Medicaid coverage as a *quid pro quo* for participation in the Program.

As a threshold matter, the IRA does not impose a “condition” for manufacturers participating in Medicare and Medicaid. The statute issues a straightforward command: provide access to selected drugs or pay a substantial penalty. *See* 42 U.S.C. § 1320f–6. Unlike the other federal programs the Government cites (Govt. Br. 1, 6, 23–24), the IRA does not propose a *quid pro quo*, rewarding participation with Medicare or Medicaid coverage or penalizing noncompliance by withholding that coverage. BMS’s products will remain covered by Medicare and Medicaid whether BMS complies with the Program or not; the only difference is whether BMS will incur an independent penalty.

Valancourt is again instructive. The statute there required copyright owners to provide copies of their works to the Library of Congress. The Government’s defense was that “a voluntary exchange for a governmental benefit” is not a taking; it claimed depositing copies was a condition of copyright protection. 82 F.4th at 1232. But the D.C. Circuit disagreed. It observed that, under the statute, owners “receive no additional benefit for the works they forfeit,” because depositing a book is not “required to continue retaining copyright.” *Id.* “While copyright owners are subject to a series of fines for failure to deposit, they retain copyright regardless of whether they pay the fines.” *Id.* That meant there was no “voluntary exchange,” as the benefit (copyright protection) was “illusory”; it was a right the owner “already enjoyed” and “untethered” to the obligation. *Id.* at 1232–34 (citing *Horne*, 576 U.S. at 366).

Likewise, the IRA cannot be characterized as offering a “voluntary exchange” because it is structured in the same impermissible way. If BMS does not comply with its new Program obligations, the consequence is *not* that it loses coverage under Medicare or Medicaid, even for Eliquis (let alone for all of its products). Rather, BMS is “subject to a series of fines” for failure to comply, but “retain[s]” its coverage rights “regardless.” *Id.* at 1232. To be sure, as discussed below, BMS can suspend the IRA’s penalties if it affirmatively withdraws all of its products from both Medicare and Medicaid. But that is a back-end workaround. As in *Valancourt*, the way Congress chose to structure the manufacturer’s direct front-end choice—comply or pay penalties—is telling. It signifies that complying with the Program is not a “quid pro quo” exchange for federal coverage; the “benefit” to BMS is “illusory” because Medicare and Medicaid coverage do not hinge on compliance. *Id.* at 1232-34. In short, the IRA is not—and Congress never intended it to be—a genuine condition on a governmental benefit. *See Cummings v. Premier Rehab Keller, PLLC*, 142 S. Ct. 1562, 1570 (2022) (Congress must impose conditions on receipt of federal funds “unambiguously”).

2. The “option” of withdrawing entirely from Medicare and Medicaid would impose enormous costs.

The Government proceeds to argue that, even though the Program is not *formally* structured as a condition on Medicare or Medicaid coverage, it is *functionally* the same because BMS can suspend the tax by opting out of Medicare and Medicaid. Govt. Br. 2, 15. *Valancourt* rejected the same argument on grounds that apply here too.

There, the Government argued that because “a copyright owner can readily disavow copyright protection and thereby avoid the deposit requirement,” the statute effectively functioned as “a voluntary exchange.” 82 F.4th at 1235. The D.C. Circuit disagreed. It granted only that, “perhaps,” a forfeiture “might arguably be voluntary” if the owner had a “simple, seamless, and transparent” opt-out mechanism that was also “costless.” *Id.* The owner did not. *See id.* Neither does BMS.

Most importantly, opting out of Medicare and Medicaid is the opposite of “costless.” In *Valancourt*, a \$125 fee made the opt-out insufficient. *See id.* at 1236-37. Here, BMS must surrender coverage of not only Eliquis but *every other product it sells*. Medicare and Medicaid comprise nearly half of the U.S. prescription drug market. Expecting BMS to disclaim half the market for *all its products* is like telling copyright owners they can avoid the deposit obligation for *one work* by abandoning copyright protection *for everything they publish*. That is not a voluntary exchange.

Nor is opting out of Medicare and Medicaid “seamless” or “transparent.” As in *Valancourt*, the “statute itself gives no indication” that withdrawing from Medicare can be readily “effectuate[d].” *Id.* at 1236. In fact, Congress expressly *blocked* manufacturers from withdrawing without providing up to 23 months’ notice—by which point it *would already be too late* to avoid the Program. *See* 42 U.S.C. § 1395w-114a(b)(4)(B)(ii). The Government responds that CMS has engineered a complicated workaround: If BMS wants to withdraw, the agency will exercise its own power to “terminate” BMS earlier. Govt. Br. 16–17. But that workaround was developed “only in the course of litigation,”

reflecting a “*post hoc*” tactic “by an agency seeking to defend past [congressional] action against attack.” *Valancourt*, 82 F.4th at 1237. That workaround is also foreclosed by the statute, which lays out two *distinct* paths for termination—either an onerous one at the manufacturer’s request, or a more flexible one when the agency invokes “good cause” to terminate the manufacturer against its will. If nothing else, CMS’s reinterpretation mid-litigation cannot be deemed “simple, seamless, and transparent.” *Id.* at 1235.

3. Leveraging existing Medicare and Medicaid coverage for other products is unconstitutionally coercive.

The IRA’s demand that BMS comply with the Program’s mandates or give up Medicare and Medicaid coverage for all of its products also violates the anti-coercion principle from *National Federation of Independent Business v. Sebelius*, 567 U.S. 519 (2012) (*NFIB*). The Government makes the same argument here that the Court rejected there: that the Constitution imposes no bar to “condition[ing]” federal Medicaid spending because the program is “voluntary.” *See* U.S. Medicaid Br. 22, *NFIB*, 567 U.S. 519 (No. 11-400). The Supreme Court viewed it differently.

Spending Clause regulation is only permissible if it is *genuinely* voluntary, not coercive. *See NFIB*, 567 U.S. at 578, 581 (choice must be “real,” not just “theor[etical]”). The Medicaid expansion was the latter, because it leveraged massive, pre-existing funding streams on which the States had come to rely as a “means of pressuring” them to accept federal terms that dramatically reshaped the program. *Id.* at 580.

As BMS has explained, it is hard to imagine a closer analogy to the Program. *See* BMS MSJ Br. 33–36. The two cases are parallel in all three crucial respects.

First, as in *NFIB*, BMS faces termination of *existing* funding streams—all Medicare and Medicaid coverage—if it does not comply with the Program’s mandates. The Government does not dispute that.

Second, as in *NFIB*, those funding streams are crucial to BMS’s viability, leaving it with only the illusion of choice. The Government’s only response is to mischaracterize a news article, which says that some pharmaceutical companies may, in light of the IRA, focus on developing medicines that do not prioritize the Medicare population. *See* Govt. Br. 14 n.4. In addition to being bad policy, that effect confirms the absence of any genuine choice when it comes to compliance.⁴

Third, as in *NFIB*, the new “conditions” work a fundamental revision to the original bargain. Indeed, one of the compromise elements of Medicare Part D was the provision preserving market forces by requiring price negotiations to occur between manufacturers and plan sponsors—without interference by government entities. Part D’s sponsors called this “noninterference” provision a “fundamental protection”

⁴ It also proves the innovation-stifling effects of the Program. The Government now appears to be suggesting that companies should simply avoid developing medicines for some of the neediest patients, those 65 and over or critically ill. Not only is that bad policy, it ignores the reality that no shift in drug development *today* will make a difference for the medicines *already* in the market that are now or will become subject to “negotiation” in the next decade or more.

against “price fixing by the CMS bureaucracy,” 149 Cong. Rec. S15624 (Nov. 23, 2003) (Sen. Grassley), which would “destroy” innovation, *id.* at S15631 (Sen. Frist). The IRA breaks that fundamental promise and erases longstanding expectations.

Combining these factors, the IRA coerces compliance with its new program in just the same way as in *NFIB*. That means it cannot be characterized as “voluntary.”

The Government’s attempts to distinguish *NFIB* all fail. It first tries to cabin *NFIB* as protecting only state sovereignty, not other constitutional rights. Govt. Br. 19–21. That is wrong. In *NFIB*, the Tenth Amendment and federalism were the substantive reasons why Congress could not order the States *directly* to expand Medicaid; that would have violated the anti-commandeering principle. *See NFIB*, 567 U.S. at 577–78. But *NFIB*’s rule against coercion answered a second, distinct question: whether Congress was improperly “using financial inducements” to achieve the same result—*i.e.*, to “*indirectly* coerce[] a State to adopt a federal regulatory system as its own.” *Id.* (emphasis added). The Court’s coercion analysis focused on that latter question—whether the Spending Clause path amounted to “economic dragooning” that left “no real option but to acquiesce.” *Id.* at 578, 582.

In this case, the substantive right is conferred by the Fifth Amendment, not the Tenth. It is the Takings Clause, not federalism, that prohibits Congress from ordering BMS to turn over its property. *Supra* Part I.A. But the next question—whether the Spending Clause permits the Government to do indirectly what it cannot do directly—is the same. It asks whether “persuasion [has] give[n] way to coercion.” *NFIB*, 567

U.S. at 585. That is the same test the Supreme Court has applied for at least a century in reviewing unconstitutional conditions: asking whether rights have been abridged “by the indirect ... process of requiring a surrender, which, though, in form voluntary, in fact lacks none of the elements of compulsion.” *Frost & Frost Trucking Co. v. RR. Comm’n of Cal.*, 271 U.S. 583, 593 (1926); *see also Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 607 (2013) (citing *Frost*).

Indeed, these two lines of authority—the cases like *NFIB* focused on spending inducements to cause States to forfeit sovereignty, and cases like *Frost* focused on spending inducements to cause private parties to forfeit constitutional rights—both ask whether “what cannot be done directly because of constitutional restriction cannot be done indirectly.” *Pac. Co. v. Johnson*, 285 U.S. 480, 501 (1932). And in both contexts, the Supreme Court has long answered that question by distinguishing coercion from voluntary acceptance. *See* Kathleen Sullivan, *Unconstitutional Conditions*, 102 Harv. L. Rev. 1413, 1428–34 (1989).⁵ This is the same basic inquiry applied in two parallel contexts. *See, e.g., Cummings*, 142 S. Ct. at 1570 (applying principle that Spending Clause legislation must be “voluntary” in context of private recipients); *Pace v. Bogalusa City Sch. Bd.*, 403 F.3d 272, 286-87 (5th Cir. 2005) (en banc) (“[T]he unconstitutional-conditions

⁵ *See also, e.g., Frost*, 271 U.S. at 593 (“compulsion”); *Steward Mach. Co. v. Davis*, 301 U.S. 548, 590 (1937) (“undue influence”); *Speiser v. Randall*, 357 U.S. 513, 518–19 (1958) (“coercing”); *United States v. Butler*, 297 U.S. 1, 71 (1936) (“coercion by economic pressure”); *Union Pac. R.R. Co. v. Pub. Serv. Comm’n*, 248 U.S. 67, 70–71 (1918) (“duress”); *Carter v. Carter Coal Co.*, 298 U.S. 238, 289 (1936) (“compulsion”).

doctrine ... is anchored at least in part in a theory of coercion”); *Koslow v. Pennsylvania*, 302 F.3d 161, 174 (3d Cir. 2002) (“The ‘unconstitutional conditions’ doctrine is based on the proposition that government incentives may be inherently coercive.”).

The Government also argues that it is exempt from *NFIB*’s coercion inquiry when it acts as a “market participant.” Govt. Br. 21. But no authority supports that distinction. Most of the Government’s authorities stand for the unremarkable point that States sometimes act as market participants rather than regulators—which matters for some *preemption* doctrines. See *Chamber of Com. of U.S. v. Brown*, 554 U.S. 60, 70 (2008) (NLRA preemption); *Associated Builders & Contractors Inc. v. City of Jersey City*, 836 F.3d 412, 417–18 (3d Cir. 2016) (ERISA preemption). The Government’s other cases hold only that States’ market activities—as opposed to regulations—are outside the scope of the Commerce Clause. *Reeves, Inc. v. Stake*, 447 U.S. 429, 435–37 (1980); *Brooks v. Vassar*, 462 F.3d 341, 358 (4th Cir. 2006). None of the Government’s cases reviewed a conditional spending program under anything like the *NFIB* coercion test—much less approved anything like the IRA’s method of coercion.

The Government also cites *Biden v. Missouri*, 142 S. Ct. 647 (2022) (per curiam), which is particularly head-scratching. Govt. Br. 22. In rejecting a challenge to HHS’s statutory authority to impose a vaccine requirement for hospitals participating in Medicare and Medicaid, the Court did not suggest that HHS was acting as a market participant, apply *NFIB*’s coercion test, or even cite *NFIB*. Nor did anyone argue that the condition failed on these or similar grounds.

In any event, the Government's claim that it enacted the IRA in its role as a market participant is fantastical. The Program is a quintessential exercise of *sovereign power*, not an everyday example of ordinary market participation. Only the Government can tax private parties who decline to obey its terms, as Congress provided in the IRA. Only the Government can legislate its own market dominance as a tool to work its will, as Congress did by enacting Medicare Part D and acquiring monopsonistic market control. And only the Government can punish obstreperous private parties by shutting them out of other markets, as the Program threatens to do. The antitrust laws prohibit private entities from abusing their market power that way (*see* BMS MSJ Br. 38–40)—a proposition the Government does not dispute. Those laws may not directly constrain the Government, to be sure. *See U.S. Postal Serv. v. Flamingo Indus. (USA) Ltd.*, 540 U.S. 736, 744–46 (2004). But the Constitution does. And the unconstitutional conditions doctrine serves a similar function, by ensuring that the Government does not abuse its market power derived from the Spending Clause to circumvent constitutional rights. That is exactly what the Program does.

Finally, the Government attempts to satisfy *NFIB* by arguing that the Program's conditions directly govern the use of the offered funds. Govt. Br. 22–23. That is just false. The IRA leverages *all* Medicare and Medicaid spending on BMS's *other* products to extract below-market sales of *one* medicine—Eliquis. The condition (giving up Eliquis at a huge discount) has nothing to do with the funds being held hostage (reimbursement for other BMS products). Thus, the Program operates differently from

one that “places a direct restriction on how a [recipient] uses [the] federal funds.” *Gruver v. La. Bd. of Supervisors*, 959 F.3d 178, 183 (5th Cir. 2020). Instead of limiting how BMS “uses” the funds it receives for other products, the Program ransoms those separate funds to coerce a distinct transaction involving a different product—Eliquis. *NFIB* prohibits exactly that.

4. Conditioning all Medicare and Medicaid coverage on compliance with the Program fails the nexus-and-proportionality standard.

Finally, the Program violates the traditional unconstitutional conditions doctrine. In the Takings Clause context, conditioning a government benefit on forfeiture of a property right is permissible only if the condition has an essential “nexus” to the benefit and is “rough[ly] proportiona[l]” to it. *Dolan v. City of Tigard*, 512 U.S. 374, 391 (1994); *see also Nollan v. Cal. Coastal Comm’n*, 483 U.S. 825, 834–37 (1987). Neither condition is satisfied here. Compelling BMS to surrender Eliquis at a discount has no “essential nexus” to Medicare or Medicaid coverage for *other* products, nor is it “proportional” to leverage *all* of the latter to induce BMS into a single transaction involving Eliquis.

Acknowledging that the Program would fail the nexus-and-proportionality test if viewed as a condition, the Government argues that the *Nollan-Dolan* test does not apply here because the Program does not involve “land-use decisions.” Govt. Br. 37. But the Supreme Court rejected that faulty attempt to cabin *Nollan-Dolan* in *Cedar Point*. There, the Government tried to characterize a physical taking as a condition on receipt of government benefits (not a zoning or land-use permit), but the Court invoked *Nollan-*

Dolan to reject that defense. 141 S. Ct. at 2079–80. It explained that the “nexus and rough proportionality requirements” were the proper “framework” for analyzing whether “the government may require property owners to cede a right of access as a condition of receiving certain benefits, without causing a taking.” *Id.* at 2079. The same question is presented here. The *Nollan-Dolan* test is therefore the right framework here too, and the Program cannot survive it. *See Horne*, 576 U.S. at 366 (citing *Nollan* in rejecting effort to characterize raisin appropriation as “voluntary exchange”).

The Supreme Court’s earlier decision in *City of Monterey v. Del Monte Dunes at Monterey, Ltd.*, 526 U.S. 687 (1999), is not to the contrary. *Contra* Govt. Br. 37. *Monterey* held that “it was unnecessary for the [Ninth Circuit] to discuss rough proportionality,” because the jury instructions in that case “did not mention” that standard, which was “not readily applicable” to a case challenging a “denial of development.” 526 U.S. at 703. But this case does not involve a denial of development. Rather, this case, like *Cedar Point*, involves a law conditioning government benefits on the provision of access to property. The condition therefore must be related and proportional. It is neither.

* * *

In the end, regardless of exactly how the standard is framed, the Government cannot deny that its spending conditions must satisfy some constitutional standard. Threatening to strip BMS of essential, distinct, and pre-existing funding streams, amounting to nearly half the U.S. market, to induce BMS to surrender access to its property (*Eliquis*) is an unconstitutional condition under any standard.

E. The Government’s Authorities Are Off-Point or Outdated, and Its Analogies Are Inapposite.

To claim that participation in the Program is “voluntary,” the Government relies on scattered, inapposite, out-of-circuit cases describing other Medicare provisions as “voluntary.” But those cases do not—and could not—excuse all spending conditions from judicial scrutiny. That would prove far too much and, moreover, would fly in the face of consistent Supreme Court precedent. Rather, these cases simply confirm that the critical question is whether the IRA’s mandates are actually “voluntary” for BMS. To answer that question, the Court must apply *NFIB*, *Horne*, and *Nollan-Dolan*.

None of the Government’s cases do that. Indeed, all but two of them predate the Supreme Court’s clarifications in *NFIB* and *Horne* of what “voluntary” participation means (and does not mean). *See NFIB*, 567 U.S. at 581 (recognizing that coercive conditions render participation involuntary); *Horne*, 576 U.S. at 365 (denying that ability to leave raisin market rendered participation in program voluntary). And none of the cases discussed *NFIB*’s conditions framework or applied the *Nollan-Dolan* test. *See, e.g., Minn. Ass’n of Health Care Facilities, Inc. v. Minn. Dep’t of Pub. Welfare*, 742 F.2d 442, 446-47 (8th Cir. 1984) (applying “substantive due process” test); *Burditt v. HHS*, 934 F.2d 1362, 1376 (5th Cir. 1991) (imposing no scrutiny). Unsurprisingly, some of these cases rely on reasoning that cannot be squared with more recent Supreme Court precedent. *Compare, e.g., Horne*, 576 U.S. at 365 (power to exit market did not ameliorate coercion), *with Franklin Mem. Hosp. v. Harvey*, 575 F.3d 121, 126 (1st Cir. 2009) (reasoning that

hospital could avoid mandate to provide free service by “choos[ing] to stop using its property as a hospital”). This Court should apply the frameworks the Supreme Court has adopted, not disregard them on the basis of outdated and otherwise inapplicable out-of-circuit cases.

None of the Government’s cases addressed schemes bearing any resemblance to the Program. Most involved ordinary price regulation, not a command to provide property to others. In *Bowles v. Willingham*, for example, the Supreme Court sustained a price cap imposed on property rentals during World War II, emphasizing the deference accorded to wartime legislation. 321 U.S. 503, 509–10, 517, 519 (1944). But unlike the Program, which forces BMS to sell Eliquis to Medicare at below-market pricing, the statute in *Bowles* had “no requirement that the apartments in question be used for the purposes which bring them under the Act.” *Id.* at 517.

Similarly, many of the Government’s cited cases involved healthcare providers objecting to particular Medicare reimbursement rates—but where, unlike the Program, federal law did not mandate the provision of goods or services. *See Garelick v. Sullivan*, 987 F.2d 913, 916–17 (2d Cir. 1993) (limits on amounts chargeable by physicians to Medicare patients for certain services); *Whitney v. Heckler*, 780 F.2d 963, 972 (11th Cir. 1986) (15-month freeze on fees that physicians may charge Medicare patients); *St. Francis Hosp. Ctr. v. Heckler*, 714 F.2d 872, 874–75 (7th Cir. 1983) (per curiam) (limits on fees chargeable by physicians); *Se. Ark. Hosp., Inc. v. Burnwell*, 815 F.3d 448, 449–50 (8th Cir. 2016) (statutory reimbursement cap for Medicare services); *see also Baker Cnty. Med.*

Servs., Inc. v. U.S. Atty. Gen., 763 F.3d 1274, 1279–80 (11th Cir. 2014) (mandate imposed by Florida law, but plaintiff sued only federal defendants). Those providers were free to refuse to serve Medicare patients as to any service for which the reimbursement rate was unsatisfactory. By contrast, even *Garelick* recognized the Takings Clause would require compensation if companies were “compelled to employ their property to provide services to the public.” 987 F.2d at 916. That is precisely the case here, because the Program mandates that BMS surrender access to its property (Eliquis), under threat of either ruinous financial penalties or losing access to Medicare and Medicaid for all of its medicines. The plaintiffs in these other cases faced no such dilemma—again, they were free to provide whatever mix of goods or services they wanted at the federal rates, or withhold any of those goods or services from Medicare beneficiaries.

In any event, even looking past these legal and factual distinctions, none of the Government’s cases supports its contention that the Program here is “voluntary.” *NFIB*’s coercion test and *Nollan-Dolan*’s proportionality test are fact-intensive. And this case involves unprecedented facts: (1) threatened exclusion from half the nation’s prescription drug market, (2) calamitous financial penalties, (3) extreme demands that force participation in a new and unprecedented program, and (4) a dramatic change that upended longstanding reliance on earlier congressional promises. The Government’s cases involve no such extremes. For example, *Baker County* involved a relatively modest condition—the obligation to treat federal prisoners at Medicare rates—that had been on the books for decades before the challenge. 763 F.3d at 1276.

The Government also overrelies on the Southern District of Ohio’s denial of a preliminary injunction in *Dayton Area Chamber of Commerce*. Although the *Chamber* case involves the same Program as here, the court issued only a preliminary ruling on a limited record, and addressed only a Due Process claim that BMS has never asserted. The Due Process analysis involves a different alleged property interest (the right to Medicare coverage at higher rates), a different legal framework (a multi-factor balancing test), and a different asserted injury (inadequate procedures). Under the framework that governs *here*, the Program violates the Takings Clause.⁶

Last, the Government suggests the IRA resembles other health-care programs that have existed for decades, mostly without challenge. Govt. Br. 1, 6-7. In reality, those programs materially differ in both kind and degree. None imposes penalties for non-compliance as the IRA does; none demands discounts as steep as the IRA does; and none implicates as wide a slice of the market as the IRA does. That is presumably why those programs were accepted without protest for decades, whereas *every affected manufacturer* quickly sued over the Program. *Cf. Gruver*, 959 F.3d at 184 (suggesting voluntariness is more likely when condition has existed for decades without challenge).

⁶ The *Chamber* court also erred in treating an old Sixth Circuit decision, *Baptist Hosp. East v. HHS*, 802 F.2d 860 (6th Cir. 1986), as dispositive, even as to the Due Process claim. *Baptist Hospital* involved a hospital’s bid to obtain reimbursements for services it *voluntarily* provided *for free* to *non-Medicare* patients. *See id.* at 862, 869–70 (denying “any obligation by the federal government to allay a part of [a hospital’s] financial burden resulting from bad debts and acts of charity”). As the Sixth Circuit noted, “[t]he Medicare Act does not require any provider to render free services.” *Id.* at 869. Providers therefore obviously had no right to reimbursement for those services.

* * *

To sum up, the Program violates the Fifth Amendment by requiring that BMS “provide access” to Eliquis at a mere fraction of its market value. The Government tries to avoid that straightforward claim by arguing BMS has other “options” to avoid the Program. But BMS has only one real option: submit to the Government’s demand to turn over Eliquis for less than it is worth. *See* ECF 36-1, Mancill Decl. ¶¶ 24, 34-39. That is the outcome Congress intended to achieve in the Program by threatening to impose massive penalties or strip BMS’s other medicines of coverage under Medicare and Medicaid if the company did not play ball. And that is unconstitutional. Put simply, the Program is a classic *per se* taking without just compensation.

II. THE PROGRAM VIOLATES THE FIRST AMENDMENT BY COMPELLING BMS TO EXPRESS THE GOVERNMENT’S POLITICAL MESSAGES.

A straightforward requirement to provide access to Eliquis at a discount would have served the Government’s *economic* goals (albeit by violating the Takings Clause). But, instead, the Program effectuates another constitutional violation by pairing its “access” obligations with the charade of an “agreement”—obligating BMS under threat of penalties to *agree* in a written, public document that it and CMS have determined through “negotiation” the “maximum fair price” for Eliquis. The only purpose of that unprecedented scheme is to serve the Government’s *political* objectives by concealing the nature of the Program and its constitutional defects. That regime compels BMS to speak in violation of the First Amendment.

The Government makes no attempt to argue that this scheme can survive heightened scrutiny under the First Amendment. Instead, it tries to dodge the First Amendment, by claiming that BMS does not engage in any speech at all when signing the “agreement.” But by forcing BMS to sign on the dotted line, the Program compels expression *directly*. There is nothing “incidental” about this agreement—it is the *sine qua non* of the entire scheme, disguising politically unpopular price controls by forcing the regulated parties to characterize them as politically popular “negotiations.”

Next, the Government repeats its claim that the Program is voluntary because BMS can withdraw from Medicare and Medicaid. That is not only wrong for all of the reasons BMS has explained; it is also irrelevant. The Government can *never* condition federal spending on compelled speech. Forcing BMS to repeat the Government’s political talking points about the Program is unconstitutional, regardless of whether it is framed as a condition on participation in government benefit programs.

A. The Government Cannot Force BMS To Spread Its Messages.

The Government tries to escape the First Amendment in three ways: *first*, by calling the Program’s speech burdens “incidental”; *second*, by denying that the compelled speech is “expressive”; and, *third*, by citing a boilerplate “disclaimer” that CMS injected *post hoc* into the Template Agreement to try to bolster its legality. Each of these arguments is plainly wrong under controlling Supreme Court precedent.

1. The Program's compulsion of speech is direct, not incidental.

In its first line of defense, the Government argues that the Program impacts speech only in an “incidental” way. Govt. Br. 31. It claims the Program is like “run-of-the-mill price regulation” that incidentally limits speech proposing or facilitating certain prohibited transactions. *Id.* at 32. Not at all. The Program does not contain price caps that happen to carry indirect implications for speech. Instead, the Program *directly mandates* that BMS express its assent to an “agreement” *about* the price of Eliquis, its “fairness,” and the process by which it was reached. Price regulations regulate *prices* (conduct), but the Program compels *agreements* (speech).

The Government's reliance on the principle that “the First Amendment does not prevent restrictions directed at commerce or conduct from imposing incidental burdens on speech” is therefore misplaced. *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 567 (2011). That principle applies where the law regulates conduct but affects speech downstream. For example, a ban on race-based hiring may incidentally prohibit “White Applicants Only” signs, and bans on “outdoor fires” may incidentally forbid flag-burning. *Id.* Likewise, “typical price regulation” regulates the “seller's conduct” by placing certain prices off-limits—affecting speech “indirectly” by barring the offering of those prices. *Expressions Hair Design v. Schneiderman*, 581 U.S. 37, 47 (2017). In those cases, conduct is regulated (racial discrimination; fires; charging illegal prices), while speech is burdened incidentally, only insofar as it effectuates the forbidden conduct. Such laws do not directly “dictate the content of the speech at all.” *FAIR*, 547 U.S. at 62.

In contrast, the Program does precisely that by, for example, directly requiring BMS to proclaim “agree[ment]” with the “maximum fair price” set by HHS. 42 U.S.C. § 1320f–2(a). In fact, the Government admits that the “agreement” is “the core mechanism” of the Program and the “source of the enforceable obligation for manufacturers to ultimately provide their drugs at the negotiated prices.” Govt. Br. 38. That makes this case the *inverse* of scenarios where conduct is regulated and speech is only indirectly affected. Here, the Program directly compels BMS to speak (by entering the “agreement”), and that speech incidentally affects BMS’s later conduct (because the agreement obligates BMS to provide access to the medicines at the discounted price). Again, Congress did not merely cap the price of Eliquis and thereby limit BMS’s speech as a practical consequence. Quite the opposite. Congress ordered BMS to speak *about* the price HHS imposes—to express “agree[ment],” admit it is the “maximum fair price,” for Eliquis, and describe it as the product of a “negotiation.” Unlike routine price caps, laws like the Program that so directly “regulat[e] the *communication* of prices” have speech as their *object*, and thus merit heightened First Amendment scrutiny. *Expressions Hair*, 581 U.S. at 48 (emphasis added).

The cases cited by the Government are thus inapposite. The statute in *Nicopure Labs, LLC v. FDA*, 944 F.3d 267 (D.C. Cir. 2019), banned distribution of free samples of certain tobacco products. The D.C. Circuit held that it regulated only conduct, not speech—at most, by incidentally prohibiting offering the product for the price of \$0. *See id.* at 290-91; *see also Nat’l Ass’n of Tobacco Outlets, Inc. v. City of Providence*, 731 F.3d 71,

78 (1st Cir. 2013) (reasoning similarly that First Amendment does not protect “offers to engage in banned activity”). But the Program is different, as already explained. BMS is not demanding an open-ended right to advertise its prices or propose transactions (let alone prohibited transactions); rather, it seeks relief from the Program’s requirement that BMS sign an “agreement” that conveys deceptive messages *about* the CMS-dictated price for Eliquis. *Nicopure* did not address—much less endorse—anything like that.

The Government’s other cases provide no support either. The Supreme Court held in *FAIR* that providing military recruiters with equal access to campus did not compel speech. 547 U.S. at 62. That restriction regulated conduct, not speech. But it would have been a different case if the Government had instead forced universities to post fliers around campus announcing the military to be a “qualified employer” who would visit pursuant to a fully negotiated “agreement” between the university and the Pentagon. That hypothetical law would have “dictate[d] the content of the speech”—and done so intentionally to give credence to the military. *Id.* The Program operates in the same manner.

For all of the same reasons—and contrary to the Government’s overstatement—BMS’s argument does not imply that “*any* price control” violates the First Amendment by barring sellers “from expressing the idea that its products are worth more.” Govt. Br. 34. Ordinary price controls are conduct restrictions that only incidentally affect speech. So too here, the Government could have just forthrightly dictated prices at which BMS must sell—avoiding any speech problems. Instead, the Government is

forcing BMS to engage in speech intended to legitimize the Program’s extortion. There is nothing “run-of-the-mill” (*id.* at 32) about the Program’s approach.⁷

2. The compelled agreements are expressive, and intentionally so.

Next, the Government suggests that the Program’s “agreements” do not implicate the First Amendment because those documents are not “expressi[ve].” *See* Govt. Br. 31-32. That makes no sense. The agreement plainly conveys a message: BMS literally must express assent to a “maximum fair price” to which BMS supposedly will “agree” after a fake “negotiation.” That qualifies as speech under the First Amendment. Indeed, the agreement’s expressive nature—and its political import to the Government—is the only plausible reason why Congress structured the Program in such a convoluted way, instead of just imposing price controls directly.

The question of whether the Template Agreement is “expressive” is thus easily answered. As the Supreme Court has explained, the “creation and dissemination of information are speech within the meaning of the First Amendment.” *Sorrell*, 564 U.S. at 570. Indeed, “if the acts of ‘disclosing’ and ‘publishing’ information do not constitute speech, it is hard to imagine what does fall within that category.” *Bartnicki v. Vopper*,

⁷ While the Government points to 38 U.S.C. § 8126 (which governs procurement of prescription drugs by the Department of Veterans Affairs) and 42 U.S.C. § 1396r-8(b) (which forms part of the so-called 340B discount program) (Govt. Br. 24, 31-32), neither statute compels manufacturers to “agree” that the price set by the Government is the “maximum fair” one, or that it resulted from “negotiations.” That is presumably why nobody has ever challenged either of those laws on First Amendment grounds.

532 U.S. 514, 527 (2001). Thus, while First Amendment “protection does not *end* at the spoken or written word,” it certainly *starts* there. *Texas v. Johnson*, 491 U.S. 397, 404 (1989) (emphasis added). Consistent with that, the Supreme Court has deemed all manner of written information “speech”—regardless of its form or function. *See, e.g., Sorrell*, 546 U.S. at 570 (“sales, transfer, and use of prescriber-identifying information”); *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 481 (1995) (“information on beer labels”); *Dun & Bradstreet, Inc. v. Greenmoss Builders, Inc.*, 472 U.S. 749, 759 (1985) (plurality op.) (credit reports). Notably, the Court has recognized that “an individual’s signature will express” the messages conveyed, expressly or implicitly, by what he signs. *John Doe No. 1 v. Reed*, 561 U.S. 186, 194–95 (2010).

Under this precedent, the Template Agreement is plainly expressive. It consists of “written word[s]” attributable to BMS, *Johnson*, 491 U.S. at 404, and “publish[es] information” about BMS’s participation in the Program, *Vopper*, 532 U.S. at 527, to be “disseminat[ed]” to the public, *Sorrell*, 564 U.S. at 570. And this expression is meaningful—BMS is forced to proclaim that whatever price is dictated by CMS will be the “maximum fair price” for Eliquis, a declaration that will certainly be used against BMS in the commercial (non-Medicare) market as well.

Indeed, BMS’s agreement was plainly “inten[ded] to convey a particularized message.” *Spence v. Washington*, 418 U.S. 405, 410–11 (1974) (per curiam). The 12-page Template Agreement authored by CMS calls itself an “Agreement” nearly 50 times, and states over 20 times that the manufacturer and the Government have “agreed” or will

“agree” on various matters. *See* ECF 23–6. The document’s communicative intent could not be clearer: to (mis)inform the public that BMS and CMS “agreed” on a negotiated “maximum fair price” for Eliquis through voluntary “negotiations” while helping disguise the reality that the Government has forcibly seized the medicines by threatening penalties.

The legally binding nature of BMS’s agreement with the Government does not make it any less expressive. *See Reed*, 561 U.S. at 195 (“[W]e do not see how adding ... legal effect to an expressive activity somehow deprives that activity of its expressive component, taking it outside the scope of the First Amendment.”). Nor does it matter that the agreement also includes some *factual* information about BMS’s legal obligations. *See Riley v. Nat’l Fed’n of the Blind*, 487 U.S. 781, 797–98 (1988); *Sorrell*, 564 U.S. at 570. The Program’s compelled agreements are not *purely* “factual,” anyway, because they do not merely require BMS to acknowledge that the Program’s rules *exist*. Instead, the Program forces BMS to represent *agreement* to those mandates—including the “maximum fair prices” dictated by HHS. That agreement is pure fiction, not fact.

The Government fares no better by depicting the Program’s agreements as “ordinary” contracts with no expressive character. Govt. Br. 31. Typical contracts simply memorialize the terms of arm’s-length transactions without forcing one side to publicly “agree” to disputed political judgments (which will likely interfere with other commercial transactions, too). The Program’s “agreements” uniquely purport to conceal government mandates as voluntarily assumed commitments.

And, after all, that is the whole point. The Government claims that BMS cannot prove such intent (Govt. Br. 34), but who is kidding whom? The Government continues to falsely characterize the Program as one involving voluntary negotiations between consenting parties. Indeed, immediately after the first ten manufacturers signed the Program’s forced “agreements,” the Government touted those coerced signatures to promote its political narrative. In an Oval Office video, the President boasted that manufacturers “are coming to the negotiating table,” and the White House announced that all ten had “signed agreements to participate.”⁸ The media swiftly echoed those political talking points: “The manufacturers of 10 expensive medications have *agreed to negotiate* with the federal government for lower prices.” Michael D. Shear, *Drug Makers Agree to Negotiate With Medicare on Prices of 10 Medications*, N.Y. Times, Oct. 3, 2023 (emphasis added). The Government could not have scored these political points without compelling BMS to sign under threat of penalty. That underscores the expressive content of the agreements.

The Government has no other way to explain the Program’s sham “agreements” and fake “negotiations.” It would have been easy enough for Congress to mandate that BMS “shall not” charge certain prices for Eliquis. Instead, Congress imposed an

⁸ President Biden, X (Oct. 3, 2023, 8:05 AM), <https://twitter.com/POTUS/status/1709177956285759844?s=20>; The White House, *Biden-Harris Administration Takes Major Step Forward in Lowering Health Care Costs; Announces Manufacturers Participating in Drug Price Negotiation Program* (Oct. 3, 2023) (emphasis added).

unprecedented obligation on BMS to express its “agree[ment] with the Government’s policy.” *Agency for Int’l Dev. v. All. For Open Soc’y Int’l, Inc.*, 570 U.S. 205, 213 (2013). Conscripting BMS to repeat the Government’s political talking points on a hot-button issue strikes at the heart of the First Amendment’s protection against compelled speech, and the Government’s self-evident reasons for imposing that obligation offend the core purposes of that constitutional protection.

3. Disclaimers do not excuse compelled speech.

The Government’s reliance on a “disclaimer” in the Template Agreement (Govt. Br. 32-33) that supposedly dissociates BMS from the political messages contained therein does nothing to solve the compelled speech problem. Congress designed the Program to hinge on “agree[ments]” to negotiate, identify, and offer “maximum fair price[s].” 42 U.S.C. § 1320f–2(a). That remains the Program’s heart, notwithstanding the Government’s *post hoc* attempt amidst litigation to clean up the mess.

Compelled speech cannot be cured by ordering BMS to disclaim the very message it has been forced to transmit. BMS MSJ Br. 28–29; *see also Telescope Media Grp. v. Lucero*, 936 F.3d 740, 757 (8th Cir. 2019); *Frudden v. Pilling*, 742 F.3d 1199, 1205 (9th Cir. 2014); *Circle Sch. v. Pappert*, 381 F.3d 172, 182 (3d Cir. 2004). Ignoring all this, the Government insists that the disclaimer merely “emphasize[s] an already obvious point.” Govt. Br. 33 n.10. But if that were true, there would be no need for the disclaimer.

Shifting gears slightly, the Government emphasizes that nothing prevents BMS from sharing its own perspectives with the public. Govt. Br. 35. But there is no

authority supporting the notion that counter-speech can cure a speech compulsion—and for good reason. That would be the solution in *every one* of the Supreme Court’s compelled speech cases. If the Government’s view here were correct, there would have been no First Amendment problem in *Wooley v. Maynard* because drivers could have “disavow[ed]” New Hampshire’s license-plate motto with “a conspicuous bumper sticker.” 430 U.S. 705, 722 (1977) (Rehnquist, J., dissenting). But that view is not correct, because the First Amendment protects each American’s right to “decide for himself or herself the ideas and beliefs deserving of expression,” *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 641 (1994), and to “present their message[s] undiluted by views they d[o] not share,” *303 Creative LLC v. Elenis*, 600 U.S. 570, 586 (2023). The Program’s forced “agreements” thus violate the First Amendment even if BMS remains free to issue a press release repudiating the agreement it was forced to sign.

At bottom, neither the disclaimer nor the potential for counterspeech solves the compelled speech problem, for the fundamental reason that Congress cannot “require speakers to affirm in one breath that which they deny in the next.” *Pac. Gas & Elec. Co. v. Pub. Utils. Comm’n*, 475 U.S. 1, 16 (1986) (plurality op.).

B. The Government Cannot Condition Funding on Compelled Speech.

Predictably, the Government falls back to its claim that the Program is voluntary. Govt. Br. 31. But as explained, the Program requires BMS to participate. *Supra* Part I. “Voluntariness” is no more a solution to the Program’s compelled speech requirement than it is to the Program’s forced access requirement.

Even if the Government were correct for Takings Clause purposes, however, the First Amendment analysis would differ. BMS MSJ Br. 35. The Supreme Court has “broadly rejected the validity of limitations on First Amendment rights as a condition to the receipt of a governmental benefit.” *Elrod v. Burns*, 427 U.S. 347, 359 (1976) (plurality op.). In particular, Congress may *never* use funding conditions to “requir[e] recipients to profess a specific belief” or express “the Government’s view on an issue of public concern.” *All. for Open Soc’y*, 570 U.S. at 218. Such conditions are unconstitutional even where the funding offer is not “actually coercive.” *Id.* at 214. Accordingly, even if BMS had a viable option to escape the Program’s mandates, the law’s compelled speech requirement would remain unconstitutional.

The Government responds that Congress does not violate the First Amendment by declining to subsidize speech. Govt. Br. 37-38; *Regan v. Tax’n With Representation*, 461 U.S. 540, 545 (1983). To be sure, Congress can “define the limits of [a] ... spending program” through conditions that “specify the activities Congress wants to subsidize.” *All. for Open Soc’y*, 570 U.S. at 214–15; *see, e.g., Rust v. Sullivan*, 500 U.S. 173, 178, 196–99 (1991) (permitting Congress to support “family planning projects” without equally funding abortion). But that does not permit Congress to *compel* speech. *See Evergreen Ass’n, Inc. v. City of N.Y.*, 740 F.3d 233, 250–51 (2d Cir. 2014) (“While the government may incidentally encourage certain speech through its power to ‘choose to fund one activity to the exclusion of the other,’ it may not directly ‘mandat[e] that Plaintiffs affirmatively espouse the government’s position on a contested public issue’”).

Nor does that principle apply here, anyway, because the Program does not subsidize any speech. It instead requires BMS to express “the Government’s view[s]” on new pricing mandates. *All. for Open Soc’y*, 570 U.S. at 218. “[B]y its very nature,” that kind of condition “goes beyond defining the limits of [a] federally funded program.” *Id.*

The Government tries to lower the constitutional bar by asserting that “conditions on speech” are valid if they “pertain to the nature of the government program.” Govt. Br. 37. That misstates the rule: “Congress cannot recast a condition on funding as a mere definition of its program in every case, lest the First Amendment be reduced to a simple semantic exercise.” *Legal Servs. Corp. v. Velazquez*, 531 U.S. 533, 547 (2001). After all, “the definition of a particular program can always be manipulated to subsume the challenged condition.” *All. for Open Soc’y*, 570 U.S. at 215. If Congress limited Affordable Care Act subsidies to individuals who agreed to put “I love Obamacare” bumper stickers on their cars, the condition would similarly “pertain to the nature of the government program,” but that would obviously constitute an impermissible effort to leverage federal funding to coerce political speech.

The Government tries a similar maneuver here, pointing out that the compelled “agreements” are central to operation of the Program. Govt. Br. 38. Congress has indeed chosen to structure the scheme that way, but the point is that filtering the Program’s obligations through agreements does nothing to constrain the use of federal funds. It therefore cannot be characterized as germane to the Program’s legitimate

purposes. After all, Congress could have achieved the same ends by openly and transparently seizing the manufacturers’ property at dictated prices. *Cf. Richmond v. J.A. Croson Co.*, 488 U.S. 469, 493 (1989) (explaining that government’s failure to pursue goal through method least burdensome to constitutional rights suggests “possibility that the [government’s] motive ... was illegitimate”). The only purpose of laundering that result through signed agreements is to create the misimpression that BMS consents to a Government-mandated process and price.

Put simply, the Government cannot paper over a compelled speech requirement by baking it into a spending program. Viewed as a “condition,” the Program’s “agreement” mandate fails First Amendment scrutiny. It should therefore be enjoined.

CONCLUSION

The Court should deny the Government’s motion for summary judgment and instead enter judgment for BMS and grant its requested relief.⁹

⁹ At the end of its motion, the Government purports to reserve the right to file additional briefing on “the appropriate scope of remedy” if the Court rules in BMS’s favor. Govt. Br. 38. The Government forfeited those arguments by failing to respond to BMS’s argument that it is entitled to declaratory and injunctive relief.

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